IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Patent Application of

Maertens et al		Atty. Ref.:	**2752-31**
Serial No.	**08/836,075**	Group:	**1643**
Filed:	**April 21, 1997**	Examiner:	**Zeman**

For: **NEW SEQUENCES OF HEPATITIS C VIRUS GENOTYPES AND THEIR USE AS PROPHYLACTIC, THERAPEUTIC AND DIAGNOSTIC AGENTS**

#30 Plunkett 3/19/02

May 4, 2001

Assistant Commissioner for Patents
Washington, DC 20231

INFORMATION DISCLOSURE STATEMENT

Sir:

Consideration of the attached documents and return of an initialed copy of the attached PTO-1449 Form listing the same, are requested. No fee is believed to be required for consideration of the attached as a new Action on the merits has not been received since the case has been withdrawn from issue. See, the Decision on Petition mailed January 26, 2001. The Driesel (Archives of Virology, Vol. 139, No. 3/04, pages 379-388) is not attached and will be submitted under separate cover once received by the undersigned.

Consideration of the attached and return of an initialed copy of the attached PTO-1449 Form, pursuant to MPEP §609, are requested.

The Office is authorized to charge the undersigned's Deposit Account No. 14-1140 for any fee which is believed to be required for consideration of the attached. The

Ma rtens et al
S rial N . 08/836,075

COPY

present paper is submitted in duplicate for purposes of charging the undersigned's Deposit Account in the event a fee is required.

Respectfully submitted,

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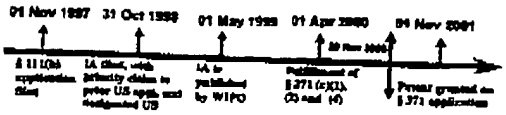
requirements that claims the benefit of the filing date of an earlier United States application has no prior art date under post-AIPA § 102(e)(2). Any United States filing date prior to the filing date of an International Application is not relevant for § 102(e)(2) prior art purposes.



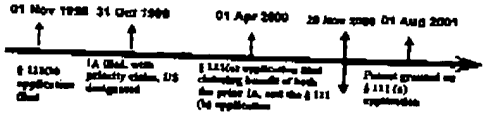
1. Post-AIPA § 102(e)(2) date of the patent: NONE
The patent is not available as prior art under post-AIPA § 102(e)(2) (because there is no date under post-AIPA § 102(e)(2)) against:
(a) any application filed on or after 29 Nov 2000; or
(b) any application which has been voluntarily published.
The patent is entitled under § 102(e) or (b) with a prior art date of 01 Nov 2001

2. Pre-AIPA § 102(e) date of the patent: 01 Apr 2000
The patent is available as prior art against:
(a) any application filed after 01 Apr 2000 but before 29 Nov 2000 which has not been voluntarily published.

Notes: (1) There is no post-AIPA § 102(e)(2) date while there is a date under pre-AIPA § 102(e).
(2) WIPO publication has a § 102(a) or (b) date of 01 May 1999.

Example 6: Reference Patent Issued from an Application filed under 35 U.S.C. § 111(a) Claiming the Benefit of an Intermediate International Application and a Prior Provisional Application.

For reference patents issued from applications filed under 35 U.S.C. § 111(a), which claim the benefit of an intermediate International Application under 35 U.S.C. §§ 120 and 365(c) and a prior United States provisional application under 35 U.S.C. §§ 119(e) and 365(c), the prior art dates accorded these reference patents are the same under pre and post-AIPA § 102(e). Thus, a patent issuing from an application filed under 35 U.S.C. § 111(a), which claims the benefit of an intermediate International Application and a prior United States provisional application, would be accorded the application's actual filing date under 35 U.S.C. § 111(a) as its prior art date.



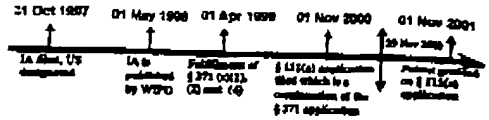
1. Post-AIPA § 102(e)(2) date of the patent: 01 Apr 2000
The patent is available as prior art against:
(a) any application filed on or after 29 Nov 2000; or
(b) any application filed after 01 Apr 2000 which has been voluntarily published.

2. Pre-AIPA § 102(e) date of the patent: 01 Apr 2000
The patent is available as prior art against:
(a) any application filed after 01 Apr 2000 but before 29 Nov 2000 which has not been voluntarily published.

Note: The post-AIPA § 102(e)(2) date and the pre-AIPA § 102(e) date are the same.

Example 7: Reference Patent issued from an Application filed under 35 U.S.C. § 111(a), which is a Continuation of the National Stage of an International Application.

For reference patents issued from applications filed under 35 U.S.C. § 111(a), which claim the benefit of the filing dates of prior International Applications pursuant to 35 U.S.C. §§ 120 and 365(c), which International Applications had complied with the National Stage requirements, the prior art dates accorded to these reference patents by post-AIPA § 102(e)(2) are different than the prior art dates accorded by pre-AIPA § 102(e). A patent issued from an application filed under 35 U.S.C. § 111(a), which was a continuation of an International Application which had complied with the National Stage requirements, will have its § 111(a) filing date as its prior art date under post-AIPA § 102(e)(2).



1. Post-AIPA § 102(e)(2) date of the patent: 01 Nov 2000
The patent is available as prior art against:
(a) any application filed on or after 29 Nov 2000; or
(b) any application filed after 1 Nov 2000 which has been voluntarily published.

2. Pre-AIPA § 102(e) date of the patent: 01 Apr 1999
The patent is available as prior art against:
(a) any application filed after 01 Apr 1999 but before 29 Nov 2000 which has not been voluntarily published.

Notes: (1) There is a different post-AIPA § 102(e)(2) date than pre-AIPA § 102(e) date.
(2) WIPO publications have a § 102(a) or (b) date of 01 May 1998.

FOR FURTHER INFORMATION CONTACT: Jeanne Clark or Robert Clarke, Legal Advisors in the Office of Patent Legal Administration, by telephone at (703) 305-1622, by fax at (703) 305-1013, or by e-mail addressed to Jeanne.Clark@USPTO.gov or Robert.Clarke@USPTO.gov.

STEPHEN G. KUNIN
Deputy Commissioner for Patent Examination Policy

Errata

"All reference to Patent No.6,180,216 to Mark John Stembardt, et al of Ohio, for TISSUE PAPER appearing in the Official Gazette of January 30, 2001 should be deleted since no patent was granted."

"All reference to Patent No. 6,180,768 to Geert Maertens, et al of Brugge, European Patent Office for NEW SEQUENCES OF HEPATITIS C VIRUS GENOTYPES AND THEIR USE AS PROPHYLACTIC, THERAPEUTIC AND DIAGNOSTIC AGENTS appearing in the Official Gazette of January 30, 2001 should be deleted since no patent was granted."

"All reference to Patent No. 6,181,581 to Robert W. Johnson Jr., et al of Raleigh, NC for MULTI-MODE POWER CONVERTERS INCORPORATING BALANCER CIRCUITS AND METHODS OF OPERATION THEREOF appearing in the Official Gazette of January 30, 2001 should be deleted since no patent was granted."

"All reference to Patent No. 6,181,986 to Toshiro Akira of Japan, for METHOD OF CORRECTING TRANSFER OF A THIN MATERIAL AND A THIN MATERIAL TRANSFER APPARATUS appearing in the Official Gazette of January 30, 2001 should be deleted since no patent was granted."

"All reference to Patent No. 6,183,061 to William E. Bland, et al of California, for HYBRID PRINTMASK FOR MULTIDROP INKJET PRINTER appearing in the Official Gazette of February 06, 2001 should be deleted since no patent was granted."

"All reference to Patent No. 6,183,983 to Haruya Sato, et al of Chiba-ken, Japan for PROTEIN MODIFICATION METHOD appearing in the Official Gazette of February 06, 2001 should be deleted since no patent was granted."

"All reference to Patent No. 6,184,240 to James Berger Camden to Ohio, for METHODS OF TREATING CANCER WITH BENZIMIDAZOLES appearing in the Official Gazette of February 06, 2001 should be deleted since no patent was granted."

"All reference to Patent No. 6,185,902 to Heinz Focke, et al of Verden, Germany for METHOD AND APPARATUS FOR HANDLING REELS appearing in the Official Gazette of February 06, 2001 should be deleted since no patent was granted."

-continued

(B) TYPE: amino acid
(D) TOPOLOGY: linear

(ii) MOLECULE TYPE: peptide

(xi) SEQUENCE DESCRIPTION: SEQ ID NO: 204:

Arg Pro Lys Tyr His Gln Val Thr Gln Asp
1 5 10

(2) INFORMATION FOR SEQ ID NO: 205:

(i) SEQUENCE CHARACTERISTICS:
(A) LENGTH: 10 amino acids
(B) TYPE: amino acid
(D) TOPOLOGY: linear

(ii) MOLECULE TYPE: peptide

(xi) SEQUENCE DESCRIPTION: SEQ ID NO: 205:

Arg Pro Arg Met His Gln Val Val Gln Glu
1 5 10

(2) INFORMATION FOR SEQ ID NO: 206:

(i) SEQUENCE CHARACTERISTICS:
(A) LENGTH: 10 amino acids
(B) TYPE: amino acid
(D) TOPOLOGY: linear

(ii) MOLECULE TYPE: peptide

(xi) SEQUENCE DESCRIPTION: SEQ ID NO: 206:

Arg Pro Arg Met Tyr Glu Ile Ala Gln Asp
1 5 10

(2) INFORMATION FOR SEQ ID NO: 207:

(i) SEQUENCE CHARACTERISTICS:
(A) LENGTH: 10 amino acids
(B) TYPE: amino acid
(D) TOPOLOGY: linear

(ii) MOLECULE TYPE: peptide

(xi) SEQUENCE DESCRIPTION: SEQ ID NO: 207:

Arg His Arg Gln His Trp Thr Val Gln Asp
1 5 10

We claim:

1. A Hepatitis C virus polynucleic acid, having a nucleotide sequence which is unique to at least one of the new HCV types 7, 9, 10 or 11, or, to at least one of the subtypes 1d, 1e, 1f, 1g, 2e, 2f, 2g, 2h, 2i, 2k, 2l, 3g, 4k, 4l or 4m, wherein when the sequence is unique to at least subtype 1d the sequence is at least 96% identical to SEQ ID NO: 1; or the complement thereof.

2. A polynucleic acid which is chosen from the group consisting of

(i) the nucleotide sequences having SEQ ID 1, 3, 5, 7, 9, 11, 13 15, 17, 19, 21, 23, 25, 27, 29, 31, 33, 35, 37, 39, 41, 43, 45, 47, 49, 51, 53, 55, 57, 59, 61, 63, 65, 67, 69, 71, 73, 75, 77, 79, 81, 83, 85, 87, 89, 91, 93, 95, 97, 99, 101, 103 or 105,

(ii) a part of said polynucleic acid of (i) which is unique to at least one of the new HCV types 7, 9, 10 or 11, or, to at least one of the subtypes 1d, 1e, 1f, 1g, 2e, 2f, 2g, 2h, 2i, 2k, 2l, 3g, 4k, 4l or 4m, wherein when the sequence is unique to at least subtype 1d the sequence is at least 96% identical to SEQ ID NO: 1, and

(iii) the complement of the polynucleic acid of (i) or (ii).

3. A polynucleic acid according to claim 1, wherein the polynucleic acid is selected from

(i) a polynucleic acid encoding an HCV polyprotein comprising in its amino acid sequence at least one of the following amino acid residues; I15, C38, V44, A49, Q43, P49, Q55, A58, S60 or D60, E68 or V68, H70, A71 or Q71 or N71, D72, H81, H101, D106, S110, L130, I134, E135, L140, S148, T150 or E150, Q153, F155, D157, G160, E165, I169, F181, L186, T190, T192 or I192 or H192, I193, A195, S196, R197 or N197 or K197, Q199 or D199 or H199 or N199, F200 or T200, A208, I213, M216 or S216, N217 or S217 or G217 or K217, T218, I219, A222, Y223, I230, W231 or L231, S232 or H232 or A232, Q233, E235 or L235, F236 or 6236, F237, I240 or M240, A242, N244, N249, I250 or K250 or R250, A252 or C252, A254,

I255 or V255, D256 or M256, E257, E260 or K260, R261, V268, S272 or R272, I285, G290 or F290, A291, A293 or L293 or W293, T294 or A294, S295 or H295, K296 or 3296, Y297 or M297, I299 or Y299, I300, S301, P316, S2646, A2648, G2649, A2650, V2652, Q2653, H2656 or L2656, F2659, K2663 or I2663, A2667 or V1667, D2677, L2681, M2686 or Q2686 or E2686, A2692 or K2692, H2697, I2707, L2708 or Y2708, A2709, A2719 or M2719, F2727, T2728 or D2728, E2729, F2730 or 72730, I2745, V2746 or E2746 or L2746 or K2746, A2748, S2749 or P2749, R2750, E2751, D2752 or N2752 or S2752 or T2752 or V2752 or I2752 or Q2752, S2753 or D2753 or G2753, D2754, A2755, L2756 or Q2756, R2757, with said notation being composed of a letter representing the amino acid residue by its one-letter code, and a number representing the amino acid numbering as shown in Table 1,

(ii) a part of said polynucleic acid of (i) which is unique to at least one of the new HCV types 7, 9, 10 or 11, or, to at least one of the subtypes 1d, 1e, 1f, 1g, 2e, 2f, 2g, 2h, 2i, 2k, 2l, 3g, 4k, 4l or 4m, wherein when the sequence is unique to at least subtype 1d the sequence is at least 96% identical to SEQ ID NO: 1,

(iii) or the complement of the polynucleic acid of (i) or (ii).

4. A polynucleic acid according to claim 1, wherein the polynucleic acid is selected from

(i) a polynucleic acid encoding an HCV polyprotein comprising in its amino acid sequences at least one amino acid sequence chosen from the group consisting of the amino acid sequences having SEQ ID 2, 4, 6, 8, 10, 12, 14, 16, 18, 20, 22, 24, 26, 28, 30, 32, 34, 40, 42, 44, 46, 48, 50, 52, 54, 56, 58, 60, 62, 64, 66, 68, 70, 72, 74, 76, 78, 78, 80, 82, 84, 86, 88, 90, 92, 94, 96, 98, 100, 102, 104 or 106,

(ii) a part of said polynucleic acid of (i) which is unique to at least one of the new HCV types 7, 9, 10 or 11, or, to at least one of the subtypes 1d, 1e, 1f, 1g, 2e, 2f, 2g, 2h, 2i, 2k, 2l, 3g, 4k, 4l or 4m, wherein when the sequence is unique to at least subtype 1d the sequence is at least 96% identical to SEQ ID NO: 1,

(iii) or the complement of the polynucleic acid of (i) or (ii).

5. A polynucleic acid according to claim 1, wherein the polynucleic acid is selected from

(i) a polynucleic acid encoding an HCV polyprotein comprising in its amino acid sequence at least one amino acid sequence chosen from the group consisting of the amino acid sequences having SEQ ID 107 to 207,

(ii) a part of said polynucleic acid of (i) which is unique to at least one of the new HCV types 7, 9, 10 or 11, or, to at least one of the subtypes 1d, 1e, 1f, 1g, 2e, 2f, 2g, 2h, 2i, 2k, 2l, 3g, 4k, 4l or 4m, wherein when the sequence is unique to at least subtype 1d the sequence is at least 96% identical to SEQ ID NO: 1,

(iii) or the complement of the polynucleic acid of (ii) or (iii).

6. A polynucleic acid according to any of claims 1 to 5 which comprises 5' UR sequences, the Core/E1 and the NS4 or the NS5B region or a part thereof.

7. A recombinant polypeptide encoded by a polynucleic acid according to any of claims 1 to 5, or a part thereof which is unique to at least one of the new HCV types 7, 9, 10 or 11, or, to at least one of the subtypes 1d, 1e, 1f, 1g, 2e, 2f, 2g, 2h, 2i, 2k, 2l, 3g, 4k, 4l or 4m, wherein when the sequence is unique to at least subtype 1d the sequence is at least 96% identical to SEQ ID NO: 1.

8. A method for production of a recombinant polypeptide, comprising:

transformation of an appropriate cellular host with a recombinant vector, in which a polynucleic acid or a part thereof according to any of claims 1 to 5 has been inserted under the control of the appropriate regulatory elements, the polynucleic acid or the part thereof thus being an insert,

culturing said transformed cellular host under conditions enabling the expression of said insert, and

harvesting said polypeptide.

9. A recombinant expression vector comprising a polynucleic acid or a part thereof according to any of claims 1 to 5 operably linked to prokaryotic, eukaryotic or viral transcription and translation control elements.

10. A host cell transformed with a recombinant vector according to claim 9.

11. A peptide corresponding to an amino acid sequence encoded by one of the polynucleic acids according to any of claims 1 to 5, with said peptide comprising an epitope which is unique to at least one of the new HCV types 7, 9, 10 or 11, or, to at least one of the subtypes 1d, 1e, 1f, 1g, 2e, 2f, 2g, 2h, 2i, 2k, 2l, 3g, 4k, 4l or 4m, wherein when the sequence is unique to at least subtype 1d the sequence is at least 96% identical to SEQ ID NO: 1.

12. The polynucleic acid of claim 1, wherein when the sequence is unique to at least subtype 1d the sequence is at least 99% identical to SEQ ID NO:1.

* * * * *